



Complete Summary

GUIDELINE TITLE

Progestogen-only implants.

BIBLIOGRAPHIC SOURCE(S)

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit.
Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive
Healthcare; 2008 Apr. 16 p. [55 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations and good practice points for clinicians on the use of progestogen-only implants as a long-term option to prevent pregnancy

TARGET POPULATION

Women considering use of progestogen-only implants as a long-term option to prevent pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Risk Assessment

1. Assessment of medical eligibility criteria for use of progestogen-only implants
2. Medical history and clinical assessment

Counseling/Management/Treatment

1. Counseling women on the risks and benefits of progestogen-only implants
 - Mode of action of progestogen-only implants
 - Duration of use
 - Contraceptive efficacy
 - Return of fertility
 - Side effects
 - Discontinuation
 - Health concerns
 - Drug interactions
 - Non-contraceptive benefits

Management/Treatment

1. Insertion of progestogen-only implants
 - Timing of insertion
 - Insertion of progestogen-only implants in special circumstances
 - Training requirements
 - Emergency services for insertions and removals

- Practical procedures for implants
- Antibiotic prophylaxis for implant procedures
- Documentation
- 2. Follow-up information after insertion of progestogen-only implants
 - Signs and symptoms requiring medical attention
 - Reducing the risk of sexually transmitted infections (STIs)
- 3. Management of problems associated with progestogen-only implant use
 - Problematic bleeding
 - Pregnancy
- 4. Removal and replacement of progestogen-only implant

MAJOR OUTCOMES CONSIDERED

- Contraceptive efficacy
- Unintended pregnancy rate
- Side effects of progestogen-only implant therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2007); EMBASE (1996–2007); PubMed (1996–2007); The Cochrane Library (to 2007) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for systematic reviews, meta-analyses and controlled trials relevant to progestogen-only implants. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization, and the British Association for Sexual Health and HIV, and reference lists of identified publications, are also searched.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

Ia Evidence obtained from meta-analysis of randomised trials

Ib Evidence obtained from at least one randomised controlled trial

IIa Evidence obtained from at least one well-designed controlled study, without randomisation

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental descriptive studies, correlation studies and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Draft One Guidance document is written, providing recommendations and good practice points based on the literature review. The Clinical Effectiveness Unit has overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible. A Multidisciplinary Group Meeting is held, comprising stakeholders and including service user representation, representation from the Faculty of Sexual and Reproductive Healthcare (FSRH) Education Committee and, where possible, representation from the FSRH Clinical Effectiveness Committee (CEC) and FSRH Council. A one-day meeting is held in Aberdeen with the Multidisciplinary Group to discuss the Draft One Guidance document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

COST ANALYSIS

Increasing the uptake of long-acting reversible contraception (LARC) methods such as the progestogen-only implant will reduce unintended pregnancies. Long-term use of the progestogen-only implant is highly cost-effective. The implant is more cost effective than combined oral contraception (even at 1 year of use) or progestogen-only injectables. The intrauterine device (IUD) is more cost-effective than the implant, but the incremental cost effectiveness ratio decreases over time. The implant is more cost-effective than the levonorgestrel-releasing intrauterine system (LNG-IUS) with up to 3 years of use, after which the LNG-IUS becomes more cost-effective.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Draft Two Guidance document is peer reviewed by the Multidisciplinary Group and the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Council (CEC). All written feedback on the Draft Two Guidance document is tabulated and the Clinical Effectiveness Unit (CEU) response to these comments is outlined. The Draft Three Guidance document is prepared based on written feedback and is sent to the Multidisciplinary Group and the FSRH CEC. In addition, two independent reviewers are identified by the CEC to provide feedback at this stage. Only minor comments can be accepted at this stage. The Final Guidance document is published by the FSRH. Proofreading of the Guidance is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A portable document format (PDF) version of the Guidance is made available on the FSRH website.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendation grades (**A to C, Good Practice Point**) are defined at the end of the "Major Recommendations" field.

Which women are eligible to use progestogen-only implants?

1. Health professionals should be familiar with the United Kingdom Medical Eligibility Criteria (UKMEC) for progestogen-only implant use (**Good Practice Point**).

Table: Definitions of *UK Medical Eligibility Criteria* for Contraceptive Use Categories

UKMEC Definition of Category	
Category	
UKMEC 1	A condition for which there is <i>no restriction</i> for the use of the contraceptive method.
UKMEC 2	A condition for which the <i>advantages of using the method generally outweigh the theoretical or proven risks</i> .
UKMEC 3	A condition where the <i>theoretical or proven risks usually outweigh the advantages</i> of using the method. ^a
UKMEC 4	A condition which represents an <i>unacceptable health risk</i> if the contraceptive method is used.

^aThe provision of a method to a woman with a condition given a UKMEC Category 3 requires expert clinical judgement and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.

What should a clinician assess when considering use of a progestogen-only implant?

2. A medical history (including sexual history) together with consideration of the recommendations in the UKMEC should be used to assess the appropriateness of the progestogen-only implant (**Good Practice Point**).

What information should be given to a woman when counseling her about a progestogen-only implant?

Mode of Action

3. Women should be informed that the primary mode of action of the progestogen-only implant is prevention of ovulation (**Grade B**).

Duration of Use

4. Women can be advised that the duration of use for the progestogen-only implant is 3 years (**Grade C**).

Contraceptive Efficacy

5. Women should be advised that the pregnancy rate associated with use of a progestogen-only implant is very low (<1 in 1000 over 3 years) (**Grade B**).
6. Women should be advised that the overall risk of ectopic pregnancy is reduced when using progestogen-only implants when compared to using no contraception (**Grade B**).
7. Women with a body mass index (BMI) >30 kg/m²; can use a progestogen-only implant without restriction and without a reduction in contraceptive efficacy for the duration of the licensed use (**Grade C**).

Return of Fertility

8. Women should be informed that there is no evidence of a delay in return of fertility following removal of a progestogen-only implant (**Grade B**).

Side Effects

Bleeding

9. Women should be informed about the likely bleeding patterns that may occur with a progestogen-only implant (**Grade C**).
10. Women should be advised that 20% of users will have no bleeding, while almost 50% will have infrequent, frequent or prolonged bleeding and that bleeding patterns are likely to remain irregular (**Grade C**).

Weight Change, Mood Change, Loss of Libido

11. Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and weight change, mood change or loss of libido (**Grade C**).

Acne

12. Women should be advised that acne may improve, occur or worsen during the use of a progestogen-only implant (**Grade C**).

Headache

13. Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and headache (**Grade C**).
14. Women of any age with a history of migraine (with or without aura) may use progestogen-only implants (**Grade C**).
15. Women who develop new symptoms of migraine without aura while using progestogen-only implants may continue the method (UKMEC 2) (**Grade C**).
16. Women who develop new symptoms of migraine with aura while using progestogen-only implants should be advised to seek medical advice as investigation may be appropriate. Continued use of progestogen-only implants may be considered (UKMEC 3) (**Grade C**).

Discontinuation

17. Clinicians should be aware that early discontinuation (up to 43% within 3 years) of progestogen-only implants is common (**Grade C**).

Health Concerns

Venous Thromboembolism

18. Women should be informed that evidence suggests there is little or no increase in risk of venous thromboembolism associated with use of a progestogen-only implant (**Grade C**).

Bone Mineral Density

19. Women should be informed that there is no evidence of a clinically significant effect on bone mineral density with use of a progestogen-only implant (**Grade B**).

Breast Cancer

There are insufficient data to make an evidence-based recommendation concerning the effect of progestogen-only implants on breast cancer risk.

Drug Interactions

20. Women using liver enzyme-inducing drugs short term (<3 weeks) may choose to continue with a progestogen-only implant. Additional contraceptive protection, such as condoms, should be used and until 4 weeks after the liver enzyme-inducing drug has been stopped. Information should be given on the use of alternative contraception if liver enzyme-inducing drugs are to be used long term (**Good Practice Point**).
21. Women should be informed that the efficacy of a progestogen-only implant is not reduced by non-liver enzyme-inducing antibiotics and that additional contraceptive protection is not required (**Grade C**).

When can a progestogen-only implant be safely inserted?

Insertion of Progestogen-only Implants in Special Circumstances

Postpartum

22. Progestogen-only implants can safely be used by women who are breastfeeding (**Grade C**).
23. Women can have a progestogen-only implant inserted up to and including Day 21 postpartum with immediate contraceptive protection. If inserted after Day 21 then condoms or abstinence should be advised for 7 days (**Grade C**).

Following Abortion or Miscarriage

24. A progestogen-only implant can be inserted immediately following surgical abortion or (second part of) medical abortion or miscarriage; no additional

contraction is required. If inserted >5 days after abortion or miscarriage then condoms or abstinence should be advised for 7 days (**Grade C**).

Table: Recommendations for Timing of Insertion of a Progestogen-only Implant as Long-term Contraception

Circumstances when progestogen-only implant is to be inserted	Recommendations for timing of insertion
General Insertion	<p>Ideally, an implant should be inserted between Days 1 and 5 (inclusive) of a normal menstrual cycle. No additional contraception is required.</p> <ul style="list-style-type: none"> • An implant can be inserted at <i>any other time in the menstrual cycle</i> if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. Additional contraception (barrier method or abstinence) should be advised for 7 days after insertion. • If the woman is amenorrhoeic, the clinician must be reasonably certain that the woman is not pregnant and that there is no risk of conception; additional contraception should be used for 7 days.
Postpartum	<p>An implant can be inserted up to Day 21 postpartum with immediate contraceptive cover. If inserted after Day 21, then condoms or abstinence should be advised for 7 days. Insertion can be prior to Day 21 but bleeding may be a problem (unlicensed use).</p>
Following miscarriage or abortion	<p>Insert on day of surgical or second part of medical abortion or immediately following miscarriage: no additional method required. If started >5 days after abortion or miscarriage additional contraception is required for 7 days (as for general insertion).</p>
<p>Switching from another method of contraception</p> <p>Combined hormonal contraception (CHC)</p>	<p>Can be inserted immediately if CHC has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. No additional contraception is required.</p>

Circumstances when progestogen-only implant is to be inserted	Recommendations for timing of insertion
<p>Progestogen-only pill (POP)</p> <p>Progestogen-only implant</p> <p>Progestogen-only injectable</p> <p>Levonorgestrel-releasing intrauterine system (LNG-IUS)</p> <p>Copper-bearing intrauterine device (IUD)</p> <p>Barrier method (i.e. male condom, female condom, cap or diaphragm)</p>	<p>Can be inserted immediately if POP has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. No additional contraception is required.</p> <p>Can be inserted immediately if previous implant was used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. No additional contraception is required.</p> <p>Should be inserted when the repeat injection was due (or up to 14 weeks since last injection). No additional contraception is required.</p> <p>Can be inserted immediately if LNG-IUS was used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant. If it is more than 5 days after the start of menstrual bleeding the LNG-IUS should be retained until the time of the woman's next menstrual period or if the woman is amenorrhoeic the LNG-IUS can be removed 7 days or more after insertion of the implant.</p> <p>Can be inserted immediately if IUD was used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant. If it is more than 5 days after the start of menstrual bleeding the IUD should be retained until the time of the woman's next menstrual period.</p> <p>Can be inserted immediately if barrier method has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. If the woman is amenorrhoeic or it has been more than 5 days since menstrual bleeding started, additional contraception should be continued for 7 days.</p>

Implant Insertion

Training Requirements

25. Health professionals who insert (and remove) progestogen-only implants should be appropriately trained, maintain competence and attend regular updates (**Grade C**).

Emergency Services for Insertions and Removals

26. Emergency equipment must be available in all settings where subdermal contraception is inserted/removed and local referral protocols must be in place for women who require further medical input (**Grade C**).

Note: See Table 3 in the original guideline document "Emergencies and insertion of subdermal implants: resuscitation measures and contents of an emergency pack".

Practical Procedures for Implants

Insertion Site

Implanon should be inserted at the inner side of the upper arm (non-dominant arm) about 6–8 cm above the elbow crease in the groove between the biceps and the triceps (sulcus bicipitalis medialis).

Aseptic Precautions and Sterile Gloves

27. An aseptic technique should be used for the insertion and removal of a progestogen-only implant (**Good Practice Point**).

Local Anaesthesia

28. Appropriate anaesthesia should be injected prior to insertion and removal of a progestogen-only implant (**Good Practice Point**).

Antibiotic Prophylaxis for Implant Procedures

29. Use of prophylactic antibiotics to prevent endocarditis is not recommended for progestogen-only implant insertion or removal (**Good Practice Point**).

Documentation

Recommendations from the Faculty of Sexual and Reproductive Healthcare (FSRH) for record keeping specific to progestogen-only implant insertion are summarised in Box 1 of the original guideline document.

What information should be given to implant users about continuation and follow-up?

Follow-up

30. Women using implants should be advised that no routine follow-up is required, but that they can return at any time to discuss problems or if that want to change their contraceptive method (**Grade C**).

Signs and Symptoms Requiring Medical Attention

31. Women using a progestogen-only implant should be advised to return if: they cannot feel their implant or it appears to have changed shape; they notice any change to the skin or pain around the site of the implant; they become pregnant; or they develop any condition which may contraindicate continuation of the method (**Good Practice Point**).

Reducing the Risk of Sexually Transmitted Infections (STIs)

32. If a woman chooses a progestogen-only implant and is at higher risk of STIs (aged <25 years, or > 25 years with a new sexual partner, or more than one partner in the last year) she should be advised to use condoms in addition (**Grade C**).

Managing Problems Associated with Progestogen-only Implant Use

Problematic Bleeding

33. Women who experience problematic bleeding while using a progestogen-only implant should have a sexual history taken to establish STI risk and/or be investigated for gynaecological pathology if clinically indicated (**Grade C**).
34. Women who experience problematic bleeding while using a progestogen-only implant and who have had gynaecological pathology excluded may be offered mefenamic acid or ethinylestradiol (alone or as an oral contraceptive) for treatment (**Grade C**).

Pregnancy

35. There is no evidence of a teratogenic effect of a progestogen-only implant, but if a user becomes pregnant and continues with the pregnancy then the implant should be removed (**Grade C**).

Implant Removal and Replacement

36. Women should be advised that fertility may return immediately after progestogen-only implant removal and effective contraception is required if pregnancy is not desired (**Grade B**).
37. Women who do not wish to have a pregnancy can be reassured that abstinence, additional contraceptive protection or emergency contraception is not necessary prior to implant removal as long as they return within 3 years, have immediate replacement or immediately start another method of contraception (**Good Practice Point**).

Complications with Removal

38. If difficulty arises with progestogen-only implant removal (due to deep insertion, failed insertion or migration) it should be localised by ultrasound before being removed. Deeply inserted implants often need to be removed by an expert (**Good Practice Point**).

Definitions:

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of a progestogen-only implants for contraception

POTENTIAL HARMS

- Bleeding patterns are likely to change during use of a progestogen-only implant. 20% of users will have no bleeding; almost 50% will have infrequent, frequent or prolonged bleeding. Bleeding patterns are likely to remain irregular over time.
- The pregnancy rate associated with the use of a progestogen-only implant is <1 in 1000 over 3 years of use.
- Women using liver enzyme-inducing drugs should use additional contraception (e.g., condoms), including up to 4 weeks after the liver enzyme-inducer has been stopped. An alternative contraceptive method should be chosen if liver enzyme inducing drugs are to be used long-term.

CONTRAINDICATIONS

CONTRAINDICATIONS

Past history of deep vein thrombosis is an absolute contraindication (UKMEC 4) for Implanon use.

QUALIFYING STATEMENTS

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This document is not intended to serve alone as a standard of medical care, as this should be determined individually based on available clinical information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. Progestogen-only implants. London (UK): Faculty of Sexual and Reproductive Healthcare; 2008 Apr. 16 p. [55 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Apr

GUIDELINE DEVELOPER(S)

Faculty of Sexual and Reproductive Healthcare - Professional Association

SOURCE(S) OF FUNDING

Faculty of Sexual and Reproductive HealthCare

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Sexual and Reproductive Health Care Web site](#).

Print copies: Available from the Faculty of Sexual and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for progestogen-only implants developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Sexual & and Reproductive Healthcare Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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Date Modified: 9/15/2008

